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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,928	02/10/2004	Wing K. Cheung	JJPR-0048/ORT-980USACON	1406

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,928	CHEUNG ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20041103*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The disclosure is objected to because of the following informalities: The status of parent application 09/545,479 in the claim for priority at page 1, lines 4-7, of the specification should be updated. Appropriate correction is required.

2. Claims 16-21, 37-42, 54, 55, 60, 66, 80, 81, 86, and 92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 16, line 4, and claim 37, line 4, "or" should be changed to "and" so that standard Markush language is used.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,696,056. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the '056 patent anticipates the instant claims.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

5. Claims 1-5, 7-10, 12, 14, 15, 22-26, 28-31, 33, 35, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 97/40850. (The examiner relies upon

U.S. Patent No. 6,120,761 as a translation of the WO Patent Application 97/40850, and all citations in the rejection are to the U.S. patent.) The WO Patent Application '850 teaches aqueous pharmaceutical compositions comprising erythropoietin; preferably comprising a sodium monohydrogen phosphate-sodium dihydrogen phosphate buffer or a citrate buffer preferably at a pH of 6.0 to 7.0; preferably comprising polysorbate 20 or polysorbate 80 preferably at a concentration of 0.05 to 0.1 mg/ml; preferably comprising an amino acid arginine, lysine or histidine; and optionally comprising a tonicity agent such as sodium chloride, mannitol, glucose, or sorbitol. The compositions of the WO Patent Application '850 do not comprise any urea or human blood product, e.g., human serum albumin. See, e.g., column 2, line 59 - column 3, line 57; column 4, lines 38-50; column 4, line 58 - column 5, line 8; and the claims. In the examples at columns 4-7, the aqueous pharmaceutical composition comprises a 10 mM phosphate buffer to achieve a pH=6.0, polysorbate 80, 1500 IU erythropoietin, sodium chloride, and various amino acids at various concentrations.

6. Claims 6, 11, 16, 27, 32, and 37 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 97/40850. Application of the WO Patent Application '850 is the same as in the above rejection of claims 1-5, 7-10, 12, 14, 15, 22-26, 28-31, 33, 35, and 36. The WO Patent Application '850 does not teach the particular pHs or dosages recited in instant claims 6, 11, 16, 27, 32, and 37, although these pHs and dosages are embraced within the preferred pH and dosage ranges taught by the WO Patent Application '850. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal pHs and dosages within the disclosed ranges of the WO

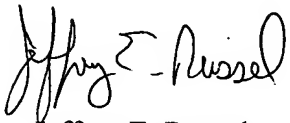
Patent Application '850 because pH and dosage are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical arts.

7. Claims 1, 2, 7, 12-14, 22, 23, 28, and 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Woog et al. Woog et al teach aqueous erythropoietin compositions comprising amino acids such as Gly, not comprising a protein stabilizer, comprising polysorbate 20, comprising NaCl, comprising a sodium phosphate buffer, and not comprising urea. See, e.g., Example 5 and Table 2, Expt. Nos. 895, 897, 899, 901, 903, 905, 907, 911, 912, and 576.

8. Claims 3-6, 8-11, 15-21, 24-27, 29-32, and 36-43 are rejected under 35 U.S.C. 103(a) as being obvious over Woog et al. Application of Woog et al is the same as in the above rejection of claims 1, 2, 7, 12-14, 22, 23, 28, and 33-35. Woog et al's specific examples use polysorbate 20 rather than polysorbate 80, although Woog et al at column 3, lines 3-9, disclose polysorbate 20 and polysorbate 80 to be preferred functional equivalents. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to substitute polysorbate 80 for the polysorbate 20 used in the specific examples of Woog et al because they are both preferred functionally equivalent wetting agents for Woog et al and the substitution of one functional equivalent for another is prima facie obvious. Woog et al do not teach Applicants' claimed component concentrations, pHs, and dosages. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal component concentrations, pHs, and dosages, for the compositions of Woog et al because concentrations, pHs, and dosages are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical arts.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

December 29, 2004